REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and the following remarks.

I. Status of the Claims

Claims 1, 3-6 and 9-22 are currently pending in the application, with claim 1 being the independent claim. Claim 8 is canceled without prejudice to or disclaimer of the subject matter therein. Claims 2 and 7 were previously canceled. Claims 21-22 are added.

Claim 1 is amended to specify that the fat phase in the composition comprises 0.5 to 2% eicosapentaen acid and/or docosahexaen acid. Support for the amendment to claim 1 may be found in paragraph [0030] at page 9 of the specification, and claim 8 as originally filed.

Newly added claim 21 specifies that eicosapentaen acid and/or docosahexaen acid are from refined fish oil concentrate. Support for new claim 21 may be found in paragraph [0028] at page 8 of the specification.

Newly added claim 22 specifies that the fat phase in the composition is melted and the fish oil concentrate is added to the fat phase immediately before homogenization with the aqueous phase. Support for new claim 22 may be found in paragraphs [0042]-[0044] at page 13 of the specification.

These amendments do not introduce any new matter into the application and their entry is respectfully requested.

II. The Rejection Under 35 U.S.C. § 102(b)

The final Office Action, at pages 2-5, maintains the rejection of claims 1, 3 and 6 under 35 U.S.C. § 102(b) as allegedly being anticipated by Alexander *et al.* (EP 0691079 A2; 1996) ("Alexander") in light of Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to

Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care, 5(2)*:127-132, March 2002; abstract only) ("Brenna").

Although it acknowledges that Alexander fails to teach eicosapentaenoic acid and/or docosahexaenoic acid, the Office Action relies on the disclosure of Brenna, for the teachings that α-linolenic acid is an omega-3 fatty acid precursor that is converted into eicosapentaenoic acid and docosahexaenoic acid, and infers from these teachings that administration of plant oils containing α-linolenic acid necessarily contains eicosapentaenoic acid and docosahexaenoic acid, because α-linolenic acid will be converted to either or both of these products.

Further, the Advisory Action alleges that the specification and claims fail to disclose how the composition of the invention is made, and the claims do not define the effective amount of eicosapentaenoic acid and/or docosahexaenoic acid required to regulate fat metabolism. Applicant respectfully traverses this ground of rejection.

1. Summary of the Claimed Invention

The presently claimed invention is directed to a method for supplementing the diet of a subject with diabetes mellitus comprising administering to the subject a composition comprising medium-chain triglycerides in an amount sufficient to regulate and normalize fat metabolism in the subject, wherein the fat phase in the composition comprises:

(a) 10 to 30% medium-chain triglycerides;

(b) at least one monounsaturated fatty acid;

(c) linoleic acid;

(d) α-linolenic acid; and

(e) ***0.5 to 2%*** eicosapentaen acid and/or docosahexaen acid as multiple unsaturated triglycerides.

Further, new claim 21 specifies that eicosapentaen acid and/or docosahexaen acid are ***from refined fish oil concentrate***.

Finally, new claim 22 specifies that the fat phase in the composition is melted and the fish oil concentrate is added to the fat phase immediately before homogenization with the aqueous phase.

2. The Cited References Fail to Teach Each and Every Element of the Claimed Invention

Alexander discloses a composition comprising canola oil, olive oil, high-oleic safflower oil and soy oil, and teaches that linolenic acid is supplied by these oils (*see* paragraph [0046] at page 4). Alexander fails to teach a composition comprising *0.5 to 2% eicosapentaen acid and/or docosahexaen acid*, as currently claimed.

Further, with regard to claim 21, the composition disclosed by Alexander contains canola oil, olive oil, high-oleic safflower oil and soy oil, which are vegetable oils, **not** fish oils. Accordingly, Alexander fails to teach a composition comprising *0.5 to 2% eicosapentaen acid and/or docosahexaen acid from refined fish oil concentrate*, as claimed in the present application.

Finally, with regard to claim 22, Alexander fails to disclose a composition wherein the fat phase in the composition is melted and the fish oil concentrate is added to the fat phase immediately before homogenization with the aqueous phase, as presently claimed.

Thus, the cited reference fails to disclose the claimed invention.

Brenna fails to remedy the deficiencies of Alexander, as the reference fails to disclose a composition comprising 0.5 to 2% eicosapentaen acid and/or docosahexaen acid, as claimed in the present application. Further, with regard to claim 21, Brenna fails to disclose a composition comprising 0.5 to 2% eicosapentaen acid and/or docosahexaen acid from refined fish oil concentrate. Moreover, with regard to claim 22, Brenna fails to disclose a composition wherein

the fat phase in the composition is melted and the fish oil concentrate is added to the fat phase immediately before homogenization with the aqueous phase.

Thus, at least for the reasons stated above, the cited references fail to anticipate the claimed invention. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

III. The Rejections Under 35 U.S.C. § 103(a)

A. The Rejection of Claims 1, 3, 6, 9 and 11-19

The Office Action, at pages 5-8, maintains the rejection of claims 1, 3, 6, 9 and 11-19 under 35 U.S.C. § 103, as allegedly being unpatentable over Alexander *et al.* (EP 0691079 A2; 1996) ("Alexander") in light of Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care, 5(2)*:127-132, March 2002; abstract only) ("Brenna"), in view of U.S. Patent No. 3,995,069 to Harries. Applicant respectfully traverses this ground of rejection.

The inability of Alexander and Brenna to teach or suggest the invention of claims 1, 3, 6 and 21-22 is demonstrated above. Harries does not remedy the deficiencies of Alexander and Brenna. Rather, Harries discloses emulsifier blends. Thus, the cited references, whether alone or in combination, fail to disclose or suggest the claimed invention.

Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

B. The Rejection of Claims 1, 3-6, 8-10 and 20

The Office Action, at pages 8-11, maintains the rejection of claims 1, 3-6, 8-10 and 20 under 35 U.S.C. § 103, as allegedly being unpatentable over Alexander *et al.* (EP 0691079 A2; 1996) ("Alexander") in light of Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid

to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care, 5(2)*:127-132, March 2002; abstract only) ("Brenna"), in view of Madigan *et al.* ("Dietary Unsaturated Fatty Acids in Type 2 Diabetes", *Diabetes Care 23*:1472-1477; 2000) ("Madigan"), Heine *et al.* ("Linoleic-Acid-Enriched Diet: Long-Term Effects on Serum Lipoprotein and Apolipoprotein Concentrations and Insulin Sensitivity in Noninsulin-Dependent Diabetic Patients", *Am J Clin Nutr, 49(3)*:448-456; 1989, Abstract Only) ("Heine") and the Merck Index ("Citric Acid", Monograph 2328, 1989; page 363). Applicant respectfully traverses this ground of rejection.

The inability of Alexander and Brenna to teach or suggest the invention of claims 1, 3, 6 and 21-22 is demonstrated above. The additional references, Madigan, Heine and the Merck Index, do not remedy the deficiencies of Alexander and Brenna, as none of these references discloses a composition comprising 0.5 to 2% eicosapentaen acid and/or docosahexaen acid, as claimed in the present application. Accordingly, the rejection is improper.

Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

CONCLUSION

All of the stated grounds of rejection have been properly traversed or rendered moot. Thus, the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date November 10, 2008

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